

REMARKS

Status of Application

No amendments are made hereby; claim 26 remains pending.

Rejection under 35 U.S.C. § 103(a)

Claim 26 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Platz et al, US 6,051,256 in view of newly-supplied US 5,580,237 to Leger.

As previously argued, Platz does not teach, disclose or suggest at least the feature of a first liquid flow channel intermediate to the first and second gas flow channels. Nor does Platz teach, disclose or suggest, with reference to amended claim 26 that the channels are annular and concentric. Indeed Fig 3 of Platz (the only Fig to depict the atomizer *per se*), shows a circular liquid feed channel, surrounded by a fluid gas channel.

By incorporating an atomizer comprising a first liquid flow channel wherein said first liquid flow channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the channel, the atomizer further comprising first and second gas flow channels for an atomizing gas flow, wherein said first liquid flow channel is intermediate to the first and second gas flow channels, said first and second gas flow channels being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, the present invention of claim 26, produces smaller and more uniform liquid droplet sizes than Platz. Additionally, the present invention of claim 26 comprising an atomizer comprising a first annular channel for a liquid flow, wherein said first annular channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the channel, the atomizer further comprising a second annular channel for an atomizing gas flow, wherein said first and second annular channels are concentric, and said second annular channel is positioned in proximity to the first annular channel so that the atomizing gas impinges the liquid thin film to produce droplets, produces smaller and more uniform liquid droplet sizes than Platz.

In respect of the rejection in view of Leger, the applicants first assert that Leger is nonanalogous art. One of the first inquiries in an obviousness analysis is whether all of the references relied on are analogous art. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Leger is directed to an oxidant nozzle used for injecting oxygen to a combustion zone to augment a combustion reaction, used for industrial incinerators, kilns, and the like. This is certainly outside the applicants' field of endeavor, that of spray drying systems for pharmaceutical formulations to result in dry powder medicines for introducing into a patient. Nor can it be said that Leger is reasonably pertinent to the particular problem with which the inventor was concerned, namely the accurate and reproducible production of particles having a well-defined and controlled particle size range, by spray drying. Applicants submit the mere fact that Leger is **devoid of any teaching or suggestion of making particles** makes Leger nonanalogous and/or inapposite. The production of particles by spray-drying is affirmatively claimed in pending claim 26. Leger is directed to mixing an oxygen stream, and an air/fuel stream, it provides high temperature combustion. As an element thereof, Leger provides for a turbulent mixing of these streams. Thus, Leger teaches, at column 4, lines 26-26: "Combustion occurs in the recirculation zone 16 and remains attached to the nozzle face." See also Fig1. Applicants' claimed atomizer geometry results in a thin-film and is engineered for optimal atomization, not recirculation/mixing to enhance combustion.

Thus, the elements of **atomizing a liquid and spreading the atomized liquid into a thin film** (affirmatively claimed in claim 31) are clearly not problems addressed by the Leger reference. In this regard Leger teaches nothing in respect of atomizing, or drying or collecting particles, all elements of applicants' claims. Leger does not concern itself with forming and collecting dry particles comprising a pharmaceutical formulation. Accordingly, the rejection of

claim 26 based in whole or in part upon Leger violates the rule of *In re Oetiker, supra*, and must be withdrawn.

Also applicable to all rejections based on Leger, the analysis of obviousness was set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In order to establish a *prima facie* case of obviousness, three basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of the references. Second, there must be a reasonable expectation of success. Finally, the prior art reference or combined references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); (emphasis added)).

The applicants respectfully traverse the rejection as failing each element of the Graham test.

Regarding the first element of the Graham test, as noted above, Leger teaches away from a combination with Platz, since Leger does not relate to particle formation. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Regarding the third element of the *Graham* test, even if Leger is combined (improperly) with Platz, the combination does not teach or suggest all the claim limitations. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In*

re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). **Leger and Platz fail to teach** at least applicants' claim elements of: an atomizer, a liquid flow channel having a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the channel, **a third gas flow channel**, a drying chamber to dry the droplets to form particles, a collector to collect the particles.

In particular, Leger and Platz **do not teach** applicants' claimed arrangement wherein there is a liquid flow channel intermediate to a first and a second gas flow channel. In fact, applicants submit that Leger teaches only two channels, a central oxygen channel and a surrounding fuel/air channel. Note that both of the alleged channels 18 and 19 of Leger are described as being for the same purpose: "fuel or a fuel/air mixture" (see Column 4, lines 10-15). Since they are concentric, and carry the same gas, applicants submit that there is no teaching of discrete channels.

Regarding the second element of the Graham test, applicants submit that the facts articulated in respect of the first and third elements lead to no reasonable expectation of success.

For these reasons, the rejection of claim 26 violates the *Graham* test, and the withdrawal of the rejection of claim 26 is respectfully requested.

CONCLUSION

In view of the foregoing arguments, applicants respectfully request withdrawal of the rejection of claim 26 under U.S.C. § 103(a). Applicants believe all claims now pending in this application are in condition for allowance, and the issuance of a formal Notice of Allowance is respectfully requested.


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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (650) 283-6790.

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